AUG 1 3 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
For Emit® *tox*™ Salicylic Acid Assay

K011878

I. Manufacturer and Contact Information:

Manufacturer: Syva Company - Dade Behring Inc.
20400 Mariani Avenue
Cupertino, CA 95014

Contact Information: Susan L. Collins
Syva Company
20400 Mariani Avenue
Cupertino, CA 95014
Tel: 408-366-3908

II. Device Classification Name:

Salicylate test system has been classified as Class II by the Clinical Chemistry and Clinical Toxicology Devices Panel, 91 DKJ, 21 CFR 862.3830.

III. Intended Use:

Emit® *tox*™ Salicylic Acid Assay is a homogeneous enzyme immunoassay. The assay is intended for use in the quantitative analysis of salicylic acid in human serum or plasma.

IV. Device Description and Characteristics:

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

The Emit® *tox*™ Salicylic Acid Assay is a homogenous enzyme assay intended for use in quantitative analysis of Salicylic Acid in human serum or plasma. The Emit *tox*™ Salicylic Acid Assay and Calibrators have been found to be equivalent to the predicate device: Abbott AxSYM® Salicylate Assay (K951290) with regard to intended use, assay sample, and overall performance characteristics.

Specificy: Compounds, whose chemical structure would suggest possible cross-reactivity or other therapeutics concurrently used, when tested on the Emit® *tox*™ Salicylic Acid Assay, did not interfere at the levels tested.

Comparative Analysis: The Emit® *tox*™ Salicylic Acid Assay and calibrators showed excellent correlation to the predicate method. The comparative analysis to the predicate method resulted in a correlation of 0.993 with a slope value of 0.941.

Precision: A Precision study was performed and the Emit® *tox*™ Salicylic Acid Assay demonstrated acceptable within-run precision with coefficients of variation (%CV) ranging from 2.9% to 4.5% and acceptable total precision with coefficients of variation (%CV) ranging from 3.9% to 5.8%.

Spike Recovery: A spike recovery study was performed using 7 levels of spiked salicylic acid. The recovery ranged from 91.8% to 104.7%.

Sensitivity: The sensitivity level of the Emit® *tox*™ Salicylic Acid Assay is 1.5 mg/dL Salicylic Acid. This level represents the lowest measurable concentration of salicylic acid that can be distinguished from 0 mg/dL with a confidence of 95%.

Endogenous Interference: Average recovery compared to control samples was studied separately to assess endogenous interference due to bilirubin, hemoglobin and triglycerides in the Emit® *tox*™ Salicylic Acid Assay. Average recoveries were 98.7, 99.4 and 102 percent for bilirubin, hemoglobin and triglycerides, respectively. There was no effect on the accuracy of the results.

High Sample Dilution: High sample dilution was evaluated by diluting a high spike sample four different ways. Separate 1:2 and 1:3 dilutions with Emit® *tox*™ Salicylic Acid Calibrator 0, and 1:2 and 1:3 dilutions with water for each spike sample were assayed. The recovery values ranged from 104 to 107 percent. There was no effect on the accuracy of the results.

Anticoagulants: The performance of the anticoagulants K_3EDTA, sodium citrate, sodium heparin, and potassium oxalate/sodium fluoride, as compared to serum was tested on Emit® *tox*™ Salicylic Acid Assay. Average recovery, compared to serum control ranged from 98.6 to 106.3 percent.

V. Substantial Equivalence:

In conclusion, Syva Company – Dade Behring Inc. considers the Emit® *tox*™ Salicylic Acid Assay and Emit® *tox*™ Salicylic Acid Calibrators to be substantially equivalent to the Abbott AxSYM® Salicylate Assay (K951290) with regard to intended use, assay sample, and overall performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 3 2001

Ms. Susan L. Collins
Regulatory Affairs Associate
Syva Company-Dade Behring Inc.
20400 Mariani Avenue
Cupertino, CA 95014

Re: 510(k) Number: K011878
Trade/Device Name: Emit®*tox*™ Salicylic Acid Assay and Emit®*tox*™ Salicylic Acid Calibrators
Regulation Number: 862.3830
Regulatory Class: II
Product Code: DKJ, DLJ
Dated: June 14, 2001
Received: June 15, 2001

Dear Ms. Collins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If known): K011878

Device Name: Emit® *tox*™ Salicylic Acid Assay
Emit® *tox*™ Salicylic Acid Calibrators

Indications for Use:

The Emit® *tox*™ Salicylic Acid Assay is a homogenous enzyme immunoassay intended for use in the quantitative analysis of salicylic acid in human serum or plasma. Measurements obtained from this device are used in the diagnosis and treatment of salicylic acid overdose or in monitoring levels of salicylic acid to ensure appropriate therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Kevin Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011878